Adverse Event Report

SMITH & NEPHEW, INC.,ORTHOPAEDIC DIV ECHELON HIP STEM back to search results

Event Date 12/28/2004
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
Revision surgery was performed due to the product fractured.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	HIP STEM
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC.,ORTHOPAEDIC DIV 1450 E. Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC.,ORTHOPAEDIC DIV 1450 E. Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW INC.,ORTHOPAEDIC DIV 1450 Brooks Road Memphis TN 38116
Manufacturer Contact	Jason Chamness, Reg Compliance 1450 Brooks Road Memphis , TN 38116 (901) 399 -5899
Device Event Key	574294
MDR Report Key	584463
Event Key	541085

Report Number	1020279-2005-00136
Device Sequence Number	1
Product Code	JDH
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	02/23/2005
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	03/23/2005
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	34 mo
Event Location	Hospital
Date Manufacturer Received	02/23/2005
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	
Type of Device Usage	Initial

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIVISION ECHELON HIP STEM

back to search results

Catalog Number 71340113
Event Date 01/17/2005
Event Type Injury **Patient Outcome** Hospitalization; Other Required Intervention
Event Description
It was reported that revision surgery was performed and surgical time was extended due to the hip stem broke.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	HIP STEM
Baseline Brand Name	ECHELON
Baseline Generic Name	HIP STEM
Baseline Catalogue Number	71340113
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIVISION 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIVISION 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW INC. 1450 Brooks Road Memphis TN 38116
Manufacturer Contact	Jason Chamness Specialist 1450 Brooks Road

Memphis , TN 38116
(901) 399 -5899

Device Event Key	564823
MDR Report Key	574975
Event Key	546492
Report Number	1020279-2005-00094
Device Sequence Number	1
Product Code	JDI
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	02/22/2005
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	02/22/2005
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340113
Device LOT Number	02EM08565
Was Device Available For Evaluation?	Device Returned To Manufacturer
Date Returned to Manufacturer	02/14/2005
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	22 mo
Event Location	Hospital
Date Manufacturer Received	02/01/2005
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	05/01/2002
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	

Type of Device Usage Initial

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV ECHELON FEMORAL STEM

back to search results

Catalog Number 71340613
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
Revision surgery was performed due to the product fractured while implanted.

Manufacturer Narrative
Product was evaluated and conclusion states that it fractured was due to lack of proximal bone support.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	FEMORAL STEM
Baseline Brand Name	ECHELON
Baseline Generic Name	FEMORAL STEM
Baseline Catalogue Number	71340613
Baseline Device Family	ECHELON POROUS REVISION HIP SYSTEM
Baseline Device 510(K) Number	K963486
Baseline Device PMA Number	
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	11/27/1996
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV

	1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW INC. 1450 Brooks Road Memphis TN 38116
Manufacturer Contact	Jason Chamness Specialist 1450 Brooks Road Memphis , TN 38116 (901) 399 -5899
Device Event Key	559792
MDR Report Key	569945
Event Key	541577
Report Number	1020279-2005-00075
Device Sequence Number	1
Product Code	JDI
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	02/02/2005
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	02/02/2005
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340613
Device LOT Number	71107935
Was Device Available For Evaluation?	Device Returned To Manufacturer
Date Returned to Manufacturer	01/11/2005
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	unknown
Event Location	Hospital

Date Manufacturer Received	01/07/2005
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	11/01/1997
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	Unknown
Type of Device Usage	Initial

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON FEMORAL STEM

back to search results

Catalog Number 71340614
Event Date 10/01/2004
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
It was reported that revision surgery was performed due to fracture of the device.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	FEMORAL STEM
Baseline Brand Name	ECHELON
Baseline Generic Name	FEMORAL STEM
Baseline Catalogue Number	71340614
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW, INC. 1450 Brooks Road Memphis TN 38116
Manufacturer Contact	Jason Chamness, Specialist 1450 Brooks Road Memphis , TN 38116

(901) 399 -5899

Device Event Key	552349
MDR Report Key	562619
Event Key	534466
Report Number	1020279-2004-00728
Device Sequence Number	1
Product Code	KWY
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	12/29/2004
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	12/31/2004
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340614
Device LOT Number	01BM06319
Was Device Available For Evaluation?	Device Returned To Manufacturer
Date Returned to Manufacturer	12/21/2004
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	17 mo
Event Location	Hospital
Date Manufacturer Received	12/13/2004
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	02/01/2001
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	
Type of Device Usage	Initial

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON HIP STEM

back to search results

Event Date 05/15/2004
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
It was reported that revision surgery was performed due to the pt fell and developed an infection. All components were solidly fixed.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	HIP STEM
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW, INC. 1450 Brooks Road Memphis TN 38116
Manufacturer Contact	Jason Chamness, Specialist 1450 Brooks Road Memphis , TN 38116 (901) 399 -5899
Device Event Key	529977
MDR Report Key	540669
Event Key	513404

Report Number	1020279-2004-00525
Device Sequence Number	1
Product Code	KWY
Report Source	Manufacturer
Source Type	Health Professional
Reporter Occupation	Physician
Type of Report	Initial
Report Date	08/26/2004
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	08/26/2004
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	Yes
Was the Report Sent to FDA?	No
Device Age	3 mo
Event Location	Hospital
Date Manufacturer Received	08/16/2004
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	
Type of Device Usage	Initial

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON FEMORAL STEM

back to search results

Catalog Number 71340213
Event Date 07/02/2004
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
It was reported that revision surgery was performed due to the stem broke.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	FEMORAL STEM
Baseline Brand Name	ECHELON
Baseline Generic Name	FEMORAL STEM
Baseline Catalogue Number	71340213
Baseline Device Family	ECHELON POROUS REVISION HIP SYSTEM
Baseline Device 510(K) Number	K963486
Baseline Device PMA Number	
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	11/27/1996
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
	SMITH & NEPHEW, INC.,

Manufacturer *(Section D)*	ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW INC. 1450 Brooks Road Memphis TN 38116
Manufacturer Contact	Jason Chamness Specialist 1450 Brooks Road Memphis , TN 38116 (901) 399 -5899
Device Event Key	523055
MDR Report Key	533780
Event Key	506814
Report Number	1020279-2004-00356
Device Sequence Number	1
Product Code	JDI
Report Source	Manufacturer
Source Type	Health Professional
Reporter Occupation	Physician
Type of Report	Initial
Report Date	07/12/2004
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	07/12/2004
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340213
Device LOT Number	81104087
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	Yes
Was the Report Sent to FDA?	No
Device Age	16 mo
Event Location	Hospital
Date Manufacturer Received	07/06/2004
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Is The Device Single Use?	Yes

Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	
Type of Device Usage	Initial

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC./ORTHOPAEDIC DIV. ECHELON HIP STEM back to search results

Catalog Number 71340413
Event Date 12/22/2003
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
It was rpeorted that revision surgery was performed due to a fracture of the stem.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	HIP STEM
Baseline Brand Name	ECHELON
Baseline Generic Name	HIP STEM
Baseline Catalogue Number	71340413
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC./ORTHOPAEDIC DIV. 1450 E. Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC./ORTHOPAEDIC DIV. 1450 E. Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW INC. 1450 Brooks Road Memphis TN 38116
Manufacturer Contact	Carolyn Shelton, Manager 1450 Brooks Road Memphis , TN 38116 (901) 399 -6654

Device Event Key	502083
MDR Report Key	513073
Event Key	486809
Report Number	1020279-2004-00053
Device Sequence Number	1
Product Code	KWY
Report Source	Manufacturer
Source Type	Distributor
Reporter Occupation	Other
Type of Report	Initial
Report Date	02/18/2004
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	02/20/2004
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340413
Device LOT Number	01BM06304
Was Device Available For Evaluation?	Device Returned To Manufacturer
Date Returned to Manufacturer	02/16/2004
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	20 mo
Event Location	Hospital
Date Manufacturer Received	02/16/2004
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	02/01/2001
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	
Type of Device Usage	Initial

Database last updated on July 31, 200

Center for Devices and Radiological Health / CDRH

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Smith & Nephew, Inc., Orthopaedic Division

FDA Facsimile Approval: 2/18/1998

Mfr report #: 1020279-2004-00040

User facility report #: UNK

FDA Use Only

A. Patient information

1. Patient Id.	2. Age at time of event:	3. Sex	4. Weight
UNK In confidence	UNK or Date of birth: UNK	☐ female ☐ male	UNK lbs or kgs

B. Adverse event or product problem

1. [X] Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- ☐ death
- ☐ life-threatening
- [X] hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- [X] required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event	4. Date of this report
01/06/2004	02/05/04

5. Describe event or problem

It was reported that revision surgery was reported due to a fracture of the devcie.

6. Relevant tests/laboratory data, including dates

UNK

7. Other relevant history, including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

UNK

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

1.

2.

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration)
# 1.	# 1.
# 2.	# 2.

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
# 1.	# 1. ☐ yes ☐ no ☐ doesn't apply
# 2.	# 2. ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction
# 1.	# 1.	# 1. ☐ yes ☐ no ☐ doesn't apply
# 2.	# 2.	# 2. ☐ yes ☐ no ☐ doesn't apply

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name: Echelon

2. Type of device: Femoral Stem

3. Manufacturer name & address:
Smith & Nephew Inc., Orthopaedic Div.
1450 Brooks Road
Memphis, TN 38116 USA

4. Operator of device
- [X] health professional
- ☐ lay user/patient
- ☐ other:

5. Expiration date: UNK

6.
- model # NA
- catalog # 71340213
- serial # N/A
- lot # 80806204
- other # NA

7. If implanted, give date: UNK

8. If explanted, give date: UNK

9. Device available for evaluation ? (Do not send to FDA)
☐ yes ☐ no [X] returned to manufacturer on 01/06/2004

10. Concomitant medical products and therapy dates (exclude treatment of event)
UNK

E. Initial reporter

1. Name, address & phone #
Elvin Garcia
6464 NW 5TH WAY
FORT LAUDERDALE, FL 33309 USA
305-737-0924

2. Health professional ?	3. Occupation	4. Initial reporter also sent report to FDA
☐ yes [X] no	Serv Rep	☐ yes ☐ no [X] unk

FDA 3500A - Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer, or product caused or contributed to the event.

Medication and Device Experience Report (continued)

Refer to guidelines for specific instructions

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Smith & Nephew, Inc., Orthopaedic Division

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service - Food and Drug Administration

MfR report # 1020279-2004-00040

UF/Dist. report # UNK

FDA Use Only

F For use by user facility/distributor/devices only

1. Check one: [X] user facility [ ] distributor
2. UF/ Dist report number: UNK
3. User facility or distributor name/address: UNK
4. Contact person: UNK
5. Phone number: UNK
6. Date user facility or distrib. became aware of event (mo/day/yr): UNK
7. Type of report: [ ] initial [ ] follow-up #
8. Date of this report (mo/day/yr): UNK
9. Approximate age of device: UNK
10. Event problem codes (refer to coding manual): patient code; device code
11. Report sent to FDA ? [ ] yes UNK (mo/day/yr) [ ] no
12. Location where event occurred: [X] hospital [ ] outpatient diagnostic facility [ ] home [ ] nursing home [ ] ambulatory surgical facility [ ] outpatient treatment facility [ ] other: (specify)
13. Report sent to manufacturer ? [ ] yes UNK (mo/day/yr) [ ] no
14. Manufacturer name/address: Smith & Nephew, Inc., Orthopaedic Division, 1450 Brooks Road, Memphis, TN 38116 USA

G All manufacturers

1. Contact office - name/address (& mfring site for devices): Mrs. Carolyn Shelton, Reg Compliance Manager, Smith & Nephew, Inc., Orthopaedic Division, 1450 Brooks Road, Memphis, TN 38116 USA. Site: Smith & Nephew Inc., Orthopaedic Div., 1450 Brooks Road, Memphis, TN 38116 USA
2. Phone number: (901) 399-6654
3. Report source (check all that apply): [ ] foreign [ ] study [ ] literature [ ] consumer [ ] health professional [ ] user facility [X] company representative [ ] distributor [ ] other:
4. Date received by manufacturer (mo/day/yr): 01/06/2004
5. (A)NDA # / IND # / PLA # / pre-1938 [ ] yes / OTC product [ ] yes
6. If IND, protocol #
7. Type of report (check all that apply): [ ] 5-day [ ] 15-day [ ] 10-day [ ] periodic [X] initial [ ] follow-up #
8. Adverse event term(s)
9. Mfr. report number: 1020279-2004-00040

H Device manufacturers only

1. Type of reportable event: [ ] death [X] serious injury [ ] malfunction (see guidelines) [ ] other:
2. If follow-up, what type ? [ ] correction [ ] additional information [ ] response to FDA request [ ] device evaluation
3. Device evaluated by mfr ? [ ] not returned to mfr. [ ] yes [ ] evaluation summary attached [X] no (attach page to explain why not) or provide code: 02
4. Device manufacture date (mo/yr): UNK
5. Labeled for single use ? [X] yes [ ] no
6. Evaluation codes (refer to coding manual): method; results; conclusions
7. If remedial action indicated, check type: [ ] recall [ ] repair [ ] replace [ ] relabeling [ ] other: [ ] notification [ ] inspection [ ] patient monitoring [ ] modification/ adjustment
8. Usage of device: [X] initial use of device [ ] reuse [ ] unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. [ ] Additional manufacturer narrative and/or 11. [ ] Corrected data

FDA Form 3500A - back

Medication and Device
Experience Report
(continued)

Smith & Nephew, Inc., Orthopaedic Division
Page 3 of 3

MR report #
1020279-2004-00040
UF/Dist. report #
UNK
FDA Use Only

Additional Information

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Smith & Nephew, Inc., Orthopaedic Division

FDA Facsimile Approval: 2/18/1999

MW report #: 1020279-2003-00156

DF/Dist. report #: UNK

FDA Use Only

A Patient information

1. Patient Id.	2. Age at time of event:	3. Sex	4. Weight
R.C.M. In confidence	UNK or Date of birth: UNK	☐ female ☒ male	UNK lbs or kgs

B Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- ☐ death
- ☐ life-threatening
- ☒ hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☒ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event	4. Date of this report
8/28-1998	11/13/2003

5. Describe event or problem

It was reported that revision of the hip was performed. Plantiff alledges defective components.

6. Relevant tests/laboratory data, including dates

UNK

7. Other relevant history, including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

UNK

C Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)

1.

2.

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration)
# 1.	# 1.
# 2.	# 2.

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
# 1.	# 1. ☐ yes ☐ no ☐ doesn't apply
# 2.	# 2. ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction
# 1.	# 1.	# 1. ☐ yes ☐ no ☐ doesn't apply
# 2.	# 2.	# 2. ☐ yes ☐ no ☐ doesn't apply

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

D Suspect medical device

1. Brand name: UNK

2. Type of device: Hip Stem

3. Manufacturer name & address:
Smith & Nephew Inc., Orthopaedic Div.
1450 Brooks Road
Memphis, TN 38116 USA

4. Operator of device
- ☒ health professional
- ☐ lay user/patient
- ☐ other:

5. Expiration date: N/A

6.
- model # NA
- catalog # UNK
- serial # NA
- lot # UNK
- other # N/A

7. If implanted, give date: UNK

8. If explanted, give date: 8/28/98

9. Device available for evaluation ? (Do not send to FDA)
☐ yes ☒ no ☐ returned to manufacturer on

10. Concomitant medical products and therapy dates (exclude treatment of event)
UNK

F Initial reporter

1. Name, address & phone #
Jean Mercer, S&N PRODUCT LIABILITY LITIGATION
1450 Brooks Road
MEMPHIS, TN 38116

2. Health professional ?	3. Occupation	4. Initial reporter also sent report to FDA
☐ yes ☒ no	Legal	☐ yes ☐ no ☒ unk

FDA 3500A - Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer, or product caused or contributed to the event.

Medication and Device Experience Report (continued)

Refer to guidelines for specific instructions

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Smith & Nephew, Inc., Orthopaedic Division

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service - Food and Drug Administration

Mfr report # 1020279-2003-00156
UF/Dist. report # UNK
FDA Use Only

F For use by user facility/distributor devices only

1. Check one: ☐ user facility ☐ distributor
2. UF/ Dist report number: UNK
3. User facility or distributor name/address: UNK
4. Contact person: UNK
5. Phone number: UNK
6. Date user facility or distrib. became aware of event (mo/day/yr): UNK
7. Type of report: ☐ initial ☐ follow-up #
8. Date of this report (mo/day/yr): UNK
9. Approximate age of device: UNK
10. Event problem codes (refer to coding manual): patient code; device code
11. Report sent to FDA ? ☐ yes UNK (mo/day/yr) ☐ no
12. Location where event occurred: ☒ hospital ☐ outpatient diagnostic facility ☐ home ☐ nursing home ☐ ambulatory surgical facility ☐ outpatient treatment facility ☐ other: (specify)
13. Report sent to manufacturer ? ☐ yes UNK (mo/day/yr) ☐ no
14. Manufacturer name/address: Smith & Nephew, Inc., Orthopaedic Division, 1450 Brooks Road, Memphis, TN 38116 USA

G For manufacturers

1. Contact office - name/address (& mfring site for devices): Mrs. Carolyn Shelton, Reg Compliance Manager, Smith & Nephew, Inc., Orthopaedic Division, 1450 Brooks Road, Memphis, TN 38116 USA. Site: Smith & Nephew Inc., Orthopaedic Div., 1450 Brooks Road, Memphis, TN 38116 USA
2. Phone number: (901) 399-6654
3. Report source (check all that apply): ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☐ distributor ☒ other: Legal Departme
4. Date received by manufacturer (mo/day/yr): 10/14/2003
5. (A)NDA # / IND # / PLA # / pre-1938 ☐ yes / OTC product ☐ yes
6. If IND, protocol #
7. Type of report (check all that apply): ☐ 5-day ☐ 15-day ☐ 10-day ☐ periodic ☒ initial ☐ follow-up #
8. Adverse event term(s)
9. Mfr. report number: 1020279-2003-00156

H Device manufacturers only

1. Type of reportable event: ☐ death ☒ serious injury ☐ malfunction (see guidelines) ☐ other:
2. If follow-up, what type ? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation
3. Device evaluated by mfr ? ☒ not returned to mfr. ☐ yes ☐ evaluation summary attached ☐ no (attach page to explain why not) or provide code:
4. Device manufacture date (mo/yr): UNK
5. Labeled for single use ? ☒ yes ☐ no
6. Evaluation codes (refer to coding manual): method; results; conclusions
7. If remedial action indicated, check type: ☐ recall ☐ repair ☐ replace ☐ relabeling ☐ other: ☐ notification ☐ inspection ☐ patient monitoring ☐ modification/ adjustment
8. Usage of device: ☒ initial use of device ☐ reuse ☐ unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional manufacturer narrative and/or 11. ☐ Corrected data

FDA Form 3500A - back

Experience Report
(continued)

Smith & Nephew, Inc., Orthopaedic Division
Page 3 of 3

MIR report #
1020279-2003-00156
UF/Dist. report #
UNK
FDA Use Only

Additional Information

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Smith & Nephew, Inc., Orthopaedic Division

FDA Facsimile Approval: 2/18/1999
MfR report #: 1020279-2003-00135
UF/Dist. report #: UNK
FDA Use Only

A Patient information

1. Patient Id.	2. Age at time of event:	3. Sex	4. Weight
UNK In confidence	54 or Date of birth: UNK	[X] female [ ] male	lbs or 140 kgs

B Adverse event or product problem

1. [X] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- [ ] death
- [ ] life-threatening
- [X] hospitalization - initial or prolonged
- [ ] disability
- [ ] congenital anomaly
- [X] required intervention to prevent permanent impairment/damage
- [ ] other:

3. Date of event: 10/29/2003

4. Date of this report: 09/25/2003

6. Describe event or problem

It was reported that revision sugery is scheduled due to a broken femoral stem

8. Relevant tests/laboratory data, including dates

UNK

7. Other relevant history, including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Obese

C Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)

1.

2.

2. Dose, frequency & route used

1.

2.

3. Therapy dates (if unknown, give duration)

1.

2.

4. Diagnosis for use (indication)

1.

2.

5. Event abated after use stopped or dose reduced

1. [ ] yes [ ] no [ ] doesn't apply

2. [ ] yes [ ] no [ ] doesn't apply

6. Lot # (if known)

1.

2.

7. Exp. date (if known)

1.

2.

8. Event reappeared after reintroduction

1. [ ] yes [ ] no [ ] doesn't apply

2. [ ] yes [ ] no [ ] doesn't apply

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

D Suspect medical device

1. Brand name: ECHELON

2. Type of device: FEMORAL STEM

3. Manufacturer name & address

Smith & Nephew Inc., Orthopaedic Div.
1450 Brooks Road
Memphis, TN 38116 USA

4. Operator of device

[X] health professional
[ ] lay user/patient
[ ] other:

5. Expiration date: N/A

6.

model # NA
catalog # UNK
serial # NA
lot # UNK
other # N/A

7. If implanted, give date: UNK

8. If explanted, give date: UNK

9. Device available for evaluation ? (Do not send to FDA)

[ ] yes [X] no [ ] returned to manufacturer on

10. Concomitant medical products and therapy dates (exclude treatment of event)

UNK

E Initial reporter

1. Name, address & phone #

Vance Clement, S&N IMPLANT LOANER SETS
1450 BROOKS RD
MEMPHIS, TN 38116 x 6712

2. Health professional ?

[ ] yes [X] no

3. Occupation: Product Manager

4. Initial reporter also sent report to FDA

[ ] yes [ ] no [X] unk

FDA 3500A - Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer, or product caused or contributed to the event.

Medication and Device Experience Report (continued)

Refer to guidelines for specific instructions

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Smith & Nephew, Inc., Orthopaedic Division

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service - Food and Drug Administration

Mfr report # 1020279-2003-00135
UF/Dist. report # UNK
FDA Use Only

F For use by user facility/distributor devices only

1. Check one: [X] user facility [ ] distributor
2. UF/ Dist report number: UNK
3. User facility or distributor name/address: UNK
4. Contact person: UNK
5. Phone number: UNK
6. Date user facility or distrib. became aware of event (mo/day/yr): UNK
7. Type of report: [ ] initial [ ] follow-up #
8. Date of this report (mo/day/yr): NA
9. Approximate age of device: 3 Years
10. Event problem codes (refer to coding manual): patient code; device code
11. Report sent to FDA ? [ ] yes UNK (mo/day/yr) [ ] no
12. Location where event occurred: [X] hospital [ ] outpatient diagnostic facility [ ] home [ ] nursing home [ ] ambulatory surgical facility [ ] outpatient treatment facility [ ] other:
13. Report sent to manufacturer ? [ ] yes UNK (mo/day/yr) [ ] no
14. Manufacturer name/address:
Smith & Nephew, Inc., Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116 USA

G Manufacturer

1. Contact office - name/address (& mfring site for devices):
Mr. Jason Chamness, Reg Compliance Specialist
Smith & Nephew, Inc., Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116 USA
Site: Smith & Nephew Inc., Orthopaedic Div.
1450 Brooks Road
Memphis, TN 38116 USA
2. Phone number: (901) 399-5899
3. Report source (check all that apply): [ ] foreign [ ] study [ ] literature [ ] consumer [X] health professional [ ] user facility [X] company representative [ ] distributor [ ] other:
4. Date received by manufacturer (mo/day/yr): 09/25/2003
5. (A)NDA # / IND # / PLA # / pre-1938 [ ] yes / OTC product [ ] yes
6. If IND, protocol #
7. Type of report (check all that apply): [ ] 5-day [ ] 15-day [ ] 10-day [ ] periodic [X] initial [ ] follow-up #
8. Adverse event term(s)
9. Mfr. report number: 1020279-2003-00135

H Device manufacturers only

1. Type of reportable event: [ ] death [X] serious injury [ ] malfunction (see guidelines) [ ] other:
2. If follow-up, what type ? [ ] correction [ ] additional information [ ] response to FDA request [ ] device evaluation
3. Device evaluated by mfr ? [X] not returned to mfr. [ ] yes [ ] evaluation summary attached [ ] no (attach page to explain why not) or provide code:
4. Device manufacture date (mo/yr): UNK
5. Labeled for single use ? [X] yes [ ] no
6. Evaluation codes (refer to coding manual): method; results; conclusions
7. If remedial action indicated, check type: [ ] recall [ ] repair [ ] replace [ ] relabeling [ ] other: [ ] notification [ ] inspection [ ] patient monitoring [ ] modification/ adjustment
8. Usage of device: [X] initial use of device [ ] reuse [ ] unknown
9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number:
10. [ ] Additional manufacturer narrative and/or 11. [ ] Corrected data

Medication and Device Experience Report
(continued)

Smith & Nephew, Inc., Orthopaedic Division
Page 3 of 3

Mfr report #
1020279-2003-00135
UF/Dist. report #
UNK
FDA Use Only

Additional Information

Adverse Event Report

SMITH & NEPHEW, INC., ORHTOPAEDIC DIV. ECHELON FEMORAL STEM

back to search results

Catalog Number 71340111
Event Date 04/23/2003
Event Type Injury **Patient Outcome** Hospitalization; Other Required Intervention
Event Description
Revision surgery was performed because the stem fractured.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	FEMORAL STEM
Baseline Brand Name	ECHELON
Baseline Generic Name	FEMORAL STEM
Baseline Catalogue Number	71340111
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORHTOPAEDIC DIV. 1450 E. Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORHTOPAEDIC DIV. 1450 E. Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW INC. 1450 Brooks Rd Memphis TN 38116
Manufacturer Contact	Jason Chamness, Specialist 1450 Brooks Road Memphis , TN 38116 (901) 399 -5899
Device Event Key	480826

MDR Report Key	492126
Event Key	466543
Report Number	1020279-2003-00130
Device Sequence Number	1
Product Code	JDI
Report Source	Manufacturer
Source Type	Health Professional,User facility
Reporter Occupation	Other
Type of Report	Initial
Report Date	10/24/2003
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	10/24/2003
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340111
Device LOT Number	81006370
Was Device Available For Evaluation?	Device Returned To Manufacturer
Date Returned to Manufacturer	10/01/2003
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	3 yr
Event Location	Hospital
Date Manufacturer Received	09/29/2003
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	10/01/1998
Is The Device Single Use?	Yes
Is the Device an Implant?	Yes
Is this an Explanted Device?	
Type of Device Usage	Unkown

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON HIP PROSTHESIS

back to search results

Catalog Number 71340415
Event Date 03/19/2003
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
Revision surgery occurred because the stem fractured.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	HIP PROSTHESIS
Baseline Brand Name	ECHELON
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	71340415
Baseline Device Family	ECHELON HIP SYSTEM
Baseline Device 510(K) Number	K963486
Baseline Device PMA Number	
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	11/27/1996
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd Memphis TN 38116

Manufacturer Contact	Pam Peden, Specialist 1450 Brooks Road Memphis , TN 38116 (901) 399 -5844
Device Event Key	451118
MDR Report Key	462171
Event Key	437886
Report Number	1020279-2003-00047
Device Sequence Number	1
Product Code	JDH
Report Source	Manufacturer
Source Type	Health Professional,Company Representative
Reporter Occupation	Physician
Type of Report	Initial
Report Date	05/21/2003
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	05/23/2003
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340415
Device LOT Number	81104110
Was Device Available For Evaluation?	Device Returned To Manufacturer
Date Returned to Manufacturer	05/16/2003
Is The Reporter A Health Professional?	Yes
Was the Report Sent to FDA?	No
Device Age	2.5 yr
Event Location	Hospital
Date Manufacturer Received	05/16/2003
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	11/01/1998
Is The Device Single Use?	Yes
Is the Device an Implant?	Yes
Is this an Explanted Device?	

Type of Device Usage Initial

Database last updated on July 31, 2008
